

REQUEST FOR PROPOSAL AMENDMENT NO. 02

(RFP) NO.: NIMH-03-DM-0003

TITLE: "Treatment Units for Research on Neurocognition

and Schizophrenia (TURNS)"

DATE RFP ISSUED: April 15, 2003

DATE AMENDMENT July 15, 2003

NO. 02 ISSUED:

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PROPOSALS DUE: August 15, 2003, no later than 1:30 PM local

prevailing time

To all Offerors: The purpose of this amendment is to respond to questions from offerors.

Question 1: The RFP instructions specify use of a relational database (RDBMS). The data management center with which we work does not use this type of system. Our center has a long history of managing multi-center clinical trials using standard methods. It would not be reasonable for them to change to RDMBS for this one project. May we use SAS on UNIX?

Answer: SAS or UNIX would be acceptable for managing the data connect with this project.

Question 2: The RFP (page 19) stipulates: "The DSMB must be able to receive, process, edit, correct, update, store, track, retrieve, and analyze all study data." Is this correct or is it a typographical error?

Answer: This appears to be a typographical error -- the "data coordinating center" should have these capacities, not the DSMB.

Question 3: Regarding the Business Proposal, should we provide separate budgets for each site as subcontracts to the TURNS core or should we bundle together the entire budget as a single unit, assuming that subcontracting would be done later?

Answer: Please submit separate budgets and one master budget.

Question 4: Should all the individual sites submit the Representations and Certification, and Disclosure of lobbying activities?

Answer: Representations and Certifications are "Just in Time" requirements and are therefore not necessary in the proposal to be submitted by Augusy 15 (and is requested with the final proposal revision later). However, the lobbying activity disclosure should be submitted.

Question 5: Subcontractors: Must the individual sites provide information on all the "general contract clauses applicable to cost-reimbursement subcontracts with educational institutions for research and development" as stated on page 60 of the RFP?

Answer: This section reads:

(d). Subcontractors

If subcontractors are proposed, please include a complete cost proposal in the same format as the offeror's cost proposal.

Note: Organizations that plan to enter into a subcontract with an educational concern under a contract awarded under this RFP should refer to the following Web Site for a listing of clauses that are required to be incorporated in Research & Development (R&D) subcontracts with educational institutions:

http://ocm.od.nih.gov/contracts/rfps/FDP/FDPclausecover.htm

Answer con't: If you intend to award a subcontract to an educational institution, please note that the clauses referenced above will need to be included in your subcontract agreement.